REMARKS

Upon entry of this paper, claims 1, 25, 26, 27, 44, 45, and 50 have been amended, no claims have been canceled, and no claims have been added as new claims. Thus, claims 1-27 and 44-52 are presently pending in this application. No new matter has been added.

Summary of Invention in Pending Application

Prior to discussing the substantive rejections below, applicants wish to provide a brief highlight of some of the features relating to what they regard as their invention as claimed in the pending application. This Summary is not intended to convey all of the inventive aspects of the present invention. Instead, this Summary is intended to merely point out some of the features that have been identified as relevant to the rejections stated in the Office Action.

The claimed invention provides a radially expandable fluid delivery device for delivering fluid to a treatment site within the body. Fluids, including therapeutic agents, can be delivered through the expandable walls of the fluid delivery device to effect localized treatment of sites within the body. The fluid delivery device of the present invention is constructed of a biocompatible material having a microstructure that can provide a controlled, uniform, low-velocity distribution of fluid through the walls of the fluid delivery device to effectively deliver the fluid to the treatment site without damaging tissue proximate the walls of the device. Different variations and alterations can be made to the microporous and expandable walls of the fluid delivery device to modify the flow of fluid therethrough.

Claim Rejections under 35 U.S.C. §102

Claims 1, 3, 4, 6-20, 24-27, and 44

Claims 1, 3, 4, 6-20, 24-27, and 44 were rejected under 35 U.S.C. §102(b) as being anticipated by US Patent No. 5,336,178 to Kaplan (Kaplan '178). Applicants have amended all independent claims to further clarify that the wall of the radially expandable fluid delivery device is ". . . formed of a microstructure of nodes interconnected by fibrils . . ." *See* independent claims 1, 25, 26, 27, and 44. Applicants further distinguish the claimed invention from Kaplan '178 according to the following remarks.

Claims 1, 3, 4, 6-20, 24-27, and 44 Are Novel In View Of Kaplan '178 Because Kaplan '178 Does Not Contain Pores In The Wall Of The Expandable Body Through Which Fluid Can Permeate

Applicants respectfully submit that the microporous structure of the present invention is inherent in the walls of the expandable member. This is in contrast to Kaplan '178, which contains pores along delivery conduits placed *outside* of the wall of the expandable member. The actual wall of the expandable member of Kaplan '178 does not contain ". . . at least one microporous portion having a porosity sufficient for a fluid to permeate through the wall, spaces between the nodes substantially controlling the permeation of fluid through the wall . . ." *See* claims 1, 25, 26, 27, 44, et al. Instead, the actual wall of Kaplan '178 serves only as a base for mounting a series of conduits. The conduits mounted on the outside of the base wall provide a location for a plurality of pores. Therefore, the device of Kaplan '178 does not contain the pores in the wall of the expandable body through which fluid can permeate. There is no fluid permeation through the walls of the base that supports the conduit.

Absent a microporous expandable wall through which a controlled fluid permeation can occur, Kaplan '178 cannot disclose all claimed elements of the claims 1,

3, 4, 6-20, 24-27, and 44. As such, Applicants respectfully submit that the pending claims are novel with respect to Kaplan '178.

Claims 1-4, 6-10, 13-20, 24-27, and 44-49

Claims 1-4, 6-10, 13-20, 24-27, and 44-49 were also rejected under 35 U.S.C. §102(b) as being anticipated by US Patent No. 5, 843, 069 to Butler (Butler '069). Applicants have amended all independent claims to further clarify that the wall of the radially expandable fluid delivery device is ". . . formed of a microstructure of nodes interconnected by fibrils . . ." *See* independent claims 1, 25, 26, 27, 44, and 45. Applicants further distinguish the claimed invention from Butler '069 according to the following remarks.

Claims 1-4, 6-10, 13-20, 24-27, and 44-49 Are Novel With Respect To Butler '069 Because The §102(b) Rejection Is Improper

Applicants respectfully challenge the appropriateness of Bulter '069. To constitute a proper 35 U.S.C. §102(b) rejection, "A person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . ."

The Bulter '069 invention was patented on December 1, 1998. The date of application of the present invention in the United States was October 1, 1998. Thus, Butler '069 was not patented more than one year prior to the date of application for patent. As such, Applicants respectfully submit that the asserted rejection is improper, and should be withdrawn.

Claims 1-4, 6-10, 13-20, 24-27, and 44-49 Are Further Novel With Respect To Butler '069 Because There Is No Disclosure In Butler '069 Of A Fluid Permeable Wall Expandable From A First Diameter To A Second Diameter

Applicants wish to further clarify the present invention as claimed in claims 1, 25, 26, 27, 44, and 45, and its novelty with respect to Butler '069. Claims 1, 25, 26, 27, 44, and 45 claim "A radially expandable fluid delivery device . . . being deployable from a first, reduced diameter configuration to a second, increased diameter configuration . . ." *See* claims 1, 25, 26, 27, 44, et al. There is no disclosure in Butler '069 of a device wherein the walls of the device can vary between a first, reduced diameter, to a second, increased diameter. There is additionally no disclosure in Bulter '069 of the same device walls being microporous to provide for fluid permeation in a controlled manner.

Absent the above-identified elements, independent claims 1, 25, 26, 27, 44, and 45 cannot be anticipated by Bulter '069. All claims depending from independent claims 1, 25, 26, 27, 44, and 45 also cannot be anticipated by Bulter '069 based on their dependency in addition to their own claimed characteristic. Applicant's therefore respectfully submit that the present pending claims are allowable over Bulter '069.

To constitute an anticipation under 35 U.S.C. §102, all the claimed elements must be found in exactly the same situation and united in the same way to perform the identical function in a single unit of the prior art. That is, anticipation can only be established by a single prior art reference which discloses each and every element of the claimed invention.

The Pending Claims, As Amended, Are Allowable

In light of the above comments, applicants respectfully submit that the claims of the present invention, as amended, are not anticipated by, and are therefore in condition for allowance over, the cited references.

Claim Rejections under 35 U.S.C. §103

Claims 5, 21-23, and 50-52

Claims 5, 21-23, and 50-52 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Butler '069. This rejection is respectfully, but most strenuously traversed in view of the following comments.

The Rejection Based On Butler '069 Is Improper

Applicants respectfully assert that this obviousness rejection is also improper. As stated above, Butler '069 does not qualify as prior art under 35 U.S.C. §102(b). Therefore, Butler '069 cannot be applied under 35 U.S.C. §103.

Claims 5, 21-23, and 50-52 Are Additionally Non-Obvious With Respect To Butler '069 Because Butler '069 Does Not Teach Or Suggest All Claimed Elements

In addition, Applicants have asserted that Butler '069 does not teach or suggest all elements of the claimed invention. Butler '069 does not teach or suggest "A radially expandable fluid delivery device . . . deployable from a first, reduced diameter configuration to a second, increased diameter configuration . . ." *See* claims 1, 50, et al. The device of Butler '069 does not have a first, reduced diameter from which it is designed to expand to attain a second, expanded diameter.

Absent a teaching of all of the claimed elements, there can be no obviousness rejection. As such, Applicants respectfully submit that claims 5, 21-23, and 50-52 are novel and non-obvious with respect to Butler '069.

CONCLUSION

In view of the foregoing, it is respectfully submitted that this application is now in condition for allowance. Applicant courteously solicits allowance of the claims in the form of a Notice of Allowance. Should there be any further outstanding issues of patentability following the entry of this amendment, a telephone interview is respectfully requested to resolve such issues.

Attached hereto is a marked-up version of any changes made to the Specification and/or Claims by the current Amendment. The attached page is captioned "Version With Markings To Show Changes Made".

Please charge any shortage or credit any overpayment of fees to our Deposit Account No. 12-0080. In the event that a petition for an extension of time is required to be submitted herewith, and the requisite petition does not accompany this response, the undersigned hereby petitions under 37 C.F.R. §1.136(a) for an extension of time for as many months as are required to render this submission timely. Any fee due is authorized to be charged to the aforementioned Deposit Account. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Claims 1, 25, 26, 27, 44, 45, and 50 are requested to be amended as follows:

1. (Amended) A radially expandable fluid delivery device comprising:

a member constructed of a biocompatible material, the member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall ~~having~~ being formed of a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration,

wherein the wall of the member includes at least one microporous portion having a porosity sufficient for a fluid to permeate through the wall, spaces between the nodes substantially controlling the permeation of fluid through the wall.

25. (Amended) An expandable drug delivery device comprising:

a member constructed of a biocompatible fluoropolymer material, the member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall ~~having~~ being formed of a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration upon application of an expansion force to the lumen, a least a portion of the wall having nodes oriented such that spaces between the nodes form generally aligned micro-channels oriented and extending from the inner surface to the outer surface of the wall, the micro-channels being sized to permit fluid including a therapeutic agent to permeate from the inner surface to the outer surface of the wall.

26. (Amended) A radially expandable fluid delivery device comprising:

a member constructed of a biocompatible fluoropolymer material, the member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall ~~having~~ being formed of a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration upon application of an expansion force,

wherein the wall of the member includes a first microporous portion having a porosity sufficient for a fluid to permeate through the wall and a second microporous portion spaced apart from the first microporous portion and having a porosity sufficient for a fluid to permeate through the wall.

27. (Amended) A radially expandable fluid delivery device comprising:

a member constructed of a biocompatible fluoropolymer material, the tubular member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall ~~having~~ being formed of a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration upon application of an expansion force, the wall including a microporous portion having nodes oriented such that spaces between the nodes form micro-channels extending from the inner surface to the outer surface of the wall, the micro-channels being sized to permit a fluid to permeate from the inner surface to the outer surface of the wall,

wherein the size of the micro-channels varies circumferentially about the tubular member to provide regions of greater porosity within the microporous portion.

44. (Amended) A medical treatment device comprising:

a catheter having an elongated hollow tube defining an inflation lumen extending from a proximal end to a distal end, and

a balloon constructed of a biocompatible fluoropolymer material and attached to the distal end of the tube, the balloon having a wall having a thickness extending between an inner and an outer surface and a lumen in fluid communication with the inflation

lumen of the catheter, the wall ~~having~~ being formed of a microstructure of nodes interconnected by fibrils, the balloon being deployable from a first, reduced diameter configuration to a second, increased diameter configuration,

wherein the wall of the balloon includes at least one microporous portion having a porosity sufficient for a fluid to permeate through the wall, substantially all of the nodes within the microporous portion being oriented substantially perpendicular to the longitudinal axis of the balloon.

45. (Amended) A radially expandable fluid delivery device having a longitudinal axis and a wall transverse to the longitudinal axis, the fluid delivery device comprising:

a first layer of biocompatible material ~~having~~ being formed of a microstructure of nodes interconnected by fibrils, and

a second layer of biocompatible material ~~having~~ being formed of a microstructure of nodes interconnected by fibrils, the second layer overlying the first layer, the wall of the fluid delivery device extending between an inner surface of the first layer and an outer surface of the second layer, the fluid delivery device being deployable from a first, reduced diameter configuration to a second, increased diameter configuration,

wherein the wall of the fluid delivery device ~~includes~~ is formed of at least one microporous portion having a porosity sufficient for a fluid to permeate through the wall, substantially all of the nodes within the microporous portion being oriented such that spaces between the nodes form generally aligned micro-channels oriented and extending from the inner surface of the first layer to the outer surface of the second layer, the micro-channels being sized to permit fluid to permeate from the inner surface of the first layer to the outer surface of the second layer.

50. (Amended) A radially expandable fluid delivery device comprising:

a member constructed of a biocompatible material, the member having a longitudinal axis and a wall ~~having~~ being formed of a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration,

wherein the wall of the member includes at least one microporous portion having a porosity sufficient for a fluid to permeate through the wall, the microporous portion having a hydraulic conductivity less than 1000 (cm^4/ (dyne* s)* 10^{12}).